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# How to stop smoking in pregnancy and following childbirth

#### NICE public health guidance 26 How to stop smoking in pregnancy and following childbirth

#### **Ordering information**

You can download the following documents from www.nice.org.uk/guidance/PH26

- The NICE guidance (this document) which includes all the recommendations, details of how they were developed and evidence statements.
- A quick reference guide for professionals and the public.
- Supporting documents, including an evidence review and an economic analysis.

For printed copies of the quick reference guide, phone NICE publications on 0845 003 7783 or email <u>publications@nice.org.uk</u> and quote N2198.

This guidance represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

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#### Introduction

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce public health guidance on interventions aimed at stopping smoking in pregnancy and following childbirth.

The guidance is for NHS and other commissioners, managers and practitioners who have a direct or indirect role in, and responsibility for, helping women to stop smoking in pregnancy and following childbirth. This includes those working in: local authorities, education and the wider public, private, voluntary and community sectors. It may also be of interest to women who are planning a pregnancy, those who are pregnant and those who already have children, as well as their partners and families and other members of the public.

This guidance will complement, but will not replace, other NICE guidance on smoking prevention and cessation as well as guidance on identifying and supporting people most at risk of dying prematurely and behaviour change. (For further details, see section 7.) This guidance updates recommendations on smoking in NICE's clinical guideline on antenatal care.

The Public Health Interventions Advisory Committee (PHIAC) developed these recommendations on the basis of reviews of the evidence, economic modelling, expert advice, stakeholder comments and fieldwork.

Members of PHIAC are listed in appendix A. The methods used to develop the guidance are summarised in appendix B.

Supporting documents used to prepare this document are listed in appendix E. Full details of the evidence collated, including fieldwork data and activities and stakeholder comments, are available on the NICE website, along with a list of the stakeholders involved and NICE's supporting process and methods manuals. The website address is: <a href="https://www.nice.org.uk">www.nice.org.uk</a>

This guidance was developed using the NICE public health intervention process.

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#### 1 Recommendations

This is NICE's formal guidance on how to stop smoking in pregnancy and following childbirth. When writing the recommendations, the Public Health Interventions Advisory Committee (PHIAC) (see appendix A) considered the evidence of effectiveness (including cost effectiveness), commissioned reports, expert testimony, fieldwork data and comments from stakeholders and experts. Full details are available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

The evidence statements underpinning the recommendations are listed in appendix C.

The evidence reviews, supporting evidence statements and economic modelling report are available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

#### Background

Helping pregnant women who smoke to quit involves communicating in a sensitive, client-centred manner, particularly as some pregnant women find it difficult to say that they smoke. Such an approach is important to reduce the likelihood that some of them may miss out on the opportunity to get help.

The recommendations in this guidance which refer to NHS Stop Smoking Services also apply to other, non-NHS services that offer help to quit and operate to the same standard.

NHS Stop Smoking Services are local services funded by the Department of Health to provide accessible, evidence-based and cost-effective support to people who want to stop smoking. The professionals involved may include midwives who have been specially trained to help pregnant women who smoke to quit.

#### Effective interventions

The recommendations mainly cover interventions to help pregnant women who smoke to quit. These are listed at the beginning of recommendations 4 and 5. Interventions for partners are covered in recommendation 7.

Interventions that are effective with the general population are described in: 'Brief interventions and referral for smoking cessation' (NICE public health guidance 1), 'Workplace interventions to promote smoking cessation' (NICE public health guidance 5) and 'Smoking cessation services' (NICE public health guidance 10).

No specific recommendations have been made for those planning a pregnancy or who have recently given birth. This is due to the lack of evidence available on stop-smoking interventions for these groups. It does not constitute a judgement on whether or not such interventions are effective or cost effective.

#### Whose health will benefit?

These recommendations should benefit women who smoke and who:

- are planning a pregnancy
- are already pregnant
- have an infant aged under 12 months.

They should also benefit the unborn child of a woman who smokes, any infants and children she may have, her partner and others in her household who smoke.

## Recommendation 1 Identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for midwives

#### Context

Some women find it difficult to say that they smoke because the pressure not to smoke during pregnancy is so intense. This, in turn, makes it difficult to ensure they are offered appropriate support.

A carbon monoxide (CO) test is an immediate and non-invasive biochemical method for helping to assess whether or not someone smokes. However, it is unclear as to what constitutes the best cut-off point for determining smoking

status. Some suggest a CO level as low as 3 parts per million (ppm), others use a cut-off point of 6–10 ppm.

It is important to note that CO quickly disappears from expired breath (the level can fall by 50% in less than 4 hours). As a result, low levels of smoking may go undetected and may be indistinguishable from passive smoking. Conversely, environmental factors such as traffic emissions or leaky gas appliances may cause a high CO reading – as may lactose intolerance.

When trying to identify pregnant women who smoke, it is best to use a low cut-off point to avoid missing someone who may need help to quit.

#### Who should take action?

Midwives (at first maternity booking and subsequent appointments).

- Assess the woman's exposure to tobacco smoke through discussion and use of a CO test. Explain that the CO test will allow her to see a physical measure of her smoking and her exposure to other people's smoking. Ask her if she or anyone else in her household smokes. To help interpret the CO reading, establish whether she is a light or infrequent smoker. Other factors to consider include the time since she last smoked and the number of cigarettes smoked (and when) on the test day. (Note: CO levels fall overnight so morning readings may give low results.)
- Provide information (for example, a leaflet) about the risks to the unborn child of smoking when pregnant and the hazards of exposure to secondhand smoke for both mother and baby. Information should be available in a variety of formats.
- Explain about the health benefits of stopping for the woman and her baby.
   Advise her to stop not just cut down.
- Explain that it is normal practice to refer all women who smoke for help to quit and that a specialist midwife or adviser will phone and offer her

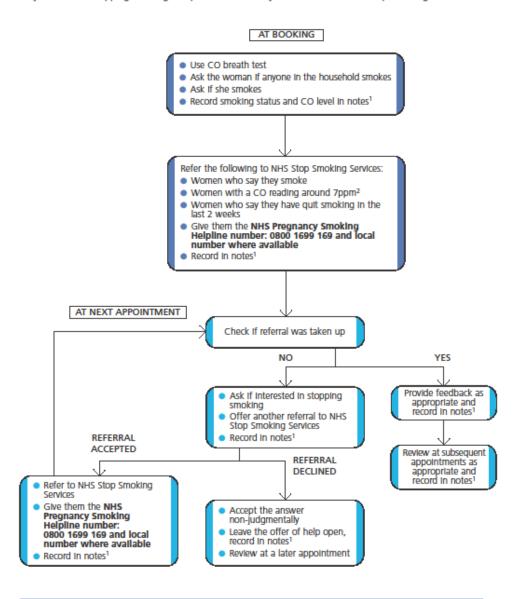
support. (Note: a specialist adviser needs to offer this support to minimise the risk of her opting out.)

- Refer all women who smoke, or have stopped smoking within the last 2 weeks, to NHS Stop Smoking Services. Also refer those with a CO reading of 7 ppm or above. (Note: light or infrequent smokers should also be referred, even if they register a lower reading for example, 3 ppm.) If they have a high CO reading (more than 10 ppm) but say they do not smoke, advise them about possible CO poisoning and ask them to call the free Health and Safety Executive gas safety advice line on: 0800 300 363.
- Use local arrangements to make the appointment and, in case they want to talk to someone over the phone in the meantime, give the NHS Pregnancy Smoking Helpline number: 0800 1699 169. Also provide the local helpline number where one is available.
- If her partner or others in the household smoke, suggest they contact NHS
   Stop Smoking Services. If no one smokes, give positive feedback.
- At the next appointment, check if the woman took up her referral. If not, ask
  if she is interested in stopping smoking and offer another referral to the
  service.
- If she accepts the referral, use local arrangements to make the appointment and give the NHS Pregnancy Smoking Helpline number: 0800 1699 169. Also provide the local helpline number where one is available.
- If she declines the referral, accept the answer in an impartial manner, leave the offer of help open. Also highlight the flexible support that many NHS Stop Smoking Services offer pregnant women (for example, some offer home visits).
- If the referral was taken up, provide feedback. Review at subsequent appointments, as appropriate.

Where appropriate, for each of the stages above record smoking status,
 CO level, whether a referral is accepted or declined and any feedback given. This should be recorded in the woman's hand-held record. If a hand-held record is not available locally, use local protocols to record this information.

### Recommendation 1: Referral pathway from maternity services to NHS Stop Smoking Services

Provide all women with information (for example, a leaflet) about the risks of smoking to her and the unborn child, including smoking by partners or family members. Address any concerns she, her partner or family may have about stopping smoking. Tell partners and family members about NHS Stop Smoking Services.



<sup>&</sup>lt;sup>1</sup> Preferably the patient handheld record.

<sup>&</sup>lt;sup>2</sup> Lower level (e.g. 3 ppm) may apply for light/infrequent smokers. Note: higher level might apply if prior exposure to other sources of pollution, e.g. traffic fumes, leaky gas appliances.

Recommendation 2 Identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for others in the public, community and voluntary sectors

#### Who should take action?

Those responsible for providing health and support services for the target group of women. This does not include midwives (see recommendation 1). It does include:

- GPs, practice nurses, health visitors and family nurses.
- Obstetricians, paediatricians, sonographers and other members of the maternity team (apart from midwives).
- Those working in youth and teenage pregnancy services, children's centres and social services.
- Those working in fertility clinics, dental practices, community pharmacies and voluntary and community organisations.

- Use any appointment or meeting as an opportunity to ask women if they smoke. If they do, explain how NHS Stop Smoking Services can help people to quit and advise them to stop.
- Offer those who want to stop a referral to NHS Stop Smoking Services.
- Use local arrangements to make a referral. Record this in the hand-held record. If a hand-held record is not available locally, use local protocols to record this information.
- Give the NHS Pregnancy Smoking Helpline number in case they want to talk to someone over the phone in the meantime: 0800 1699 169. Also provide the local helpline number where one is available.

Those with specialist training should provide pregnant women who smoke
with information (for example, a leaflet) about the risks to the unborn child
of smoking when pregnant. They should also provide information on the
hazards of exposure to secondhand smoke for both mother and baby and
on the benefits of stopping smoking. Information should be available in a
variety of formats.

### Recommendation 3 NHS Stop Smoking Services – contacting referrals

#### Who should take action?

NHS Stop Smoking Services specialist advisers.

- Telephone all women who have been referred for help. Discuss smoking and pregnancy and the issues they face, using an impartial, client-centred approach. Invite them to use the service. If necessary (and resources permitting), ring them twice and follow-up with a letter. Advise the maternity booking midwife of the outcome.
- Attempt to see those who cannot be contacted by telephone. This could happen during a routine antenatal care visit (for example, when they attend for a scan).
- Address any factors which prevent the women from using smoking
  cessation services. This could include a lack of confidence in their ability to
  quit, lack of knowledge about the services on offer, difficulty accessing
  them or lack of suitable childcare. It could also include a fear of failure and
  concerns about being stigmatised.
- If women are reluctant to attend the clinic, consider providing structured self-help materials or support via the telephone helpline. Also consider offering to visit them at home, or at another venue, if it is difficult for them to attend specialist services.

 Send information on smoking and pregnancy to those who opt out during the initial telephone call. This should include details on how to get help to quit at a later date. Such information should be easily accessible and available in a variety of formats.

### Recommendation 4 NHS Stop Smoking Services – initial and ongoing support

#### Context

Studies have shown that the following interventions are effective in helping women who are pregnant to guit smoking:

- cognitive behaviour therapy
- motivational interviewing
- structured self-help and support from NHS Stop Smoking Services.

In addition, in other countries the provision of incentives to quit has been shown to be effective with this group (research is required to see whether it would work in the UK).

Interventions using a 'stages of change' approach have had mixed success. (In some studies the approach was effective, in others it was no better than the control.) Giving pregnant women feedback on the effects of smoking on the unborn child and on their own health (such as reports of urinary cotinine levels) is not effective.

#### Who should take action?

NHS Stop Smoking Services specialist advisers.

- During the first face-to-face meeting, discuss how many cigarettes the woman smokes and how frequently. Ask if anyone else in the household smokes (this includes her partner if she has one).
- Provide information about the risks of smoking to an unborn child and the benefits of stopping for both mother and baby.

- Address any concerns she and her partner or family may have about stopping smoking and offer personalised information, advice and support on how to stop<sup>1</sup>.
- If partners or other family members are present at the first face-to-face
  meeting, encourage those who smoke to quit. If they smoke but are not at
  the meeting, ask the pregnant woman to suggest they contact NHS Stop
  Smoking Services and provide her with contact details (for example,
  telephone and address card).
- Provide the woman with intensive and ongoing support (brief interventions
  alone are unlikely to be sufficient) throughout pregnancy and beyond. This
  includes regularly monitoring her smoking status using CO tests. The latter
  may encourage her to try to quit and can also be a useful way of
  providing positive feedback once a quit attempt has been made.
- Biochemically validate that the woman has quit on the date she set and 4 weeks after. Where possible, use urine or saliva cotinine tests, as these are more accurate than CO tests and can detect exposure over the past few days rather than hours. When carrying out these tests, check whether the woman is using nicotine replacement therapy (NRT) as this may raise her cotinine levels. Note: no measure can be 100% accurate. Some people may smoke so infrequently or inhale so little that their intakes cannot reliably be distinguished from that due to passive smoking.
- If the woman says that she has stopped smoking, but the CO test reading
  is higher than 10 ppm, advise her about possible CO poisoning and ask her
  to call the free Health and Safety Executive gas safety advice line on: 0800
  300 363. However, it is more likely that she is still smoking and any further
  questions must be phrased sensitively to encourage a frank discussion.

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<sup>&</sup>lt;sup>1</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

- If she stopped smoking in the 2 weeks prior to her maternity booking appointment, continue to provide support, in line with the recommendations above and NHS Stop Smoking Services practice protocols.
- Record the method used to quit smoking, including whether or not she received help and support. Follow up 12 months after the date she set to quit.
- Establish links with contraceptive services, fertility clinics and ante- and postnatal services so that everyone working in those organisations knows about local NHS Stop Smoking Services. Ensure they understand what these services offer and how to refer people to them.

### Recommendation 5 Use of NRT and other pharmacological support

#### Context

There is mixed evidence on the effectiveness of NRT in helping women to stop smoking during pregnancy. The most robust trial to date has found no evidence that it is effective (or that it affects the child's birthweight). In addition, there are insufficient data to form a judgement about whether or not NRT has any impact on the likelihood that a child will need special care or will be stillborn.

#### Who should take action?

NHS Stop Smoking Services.

#### What action should they take?

 Discuss the risks and benefits of NRT with pregnant women who smoke, particularly those who do not wish to accept other help from NHS Stop Smoking Services. Use only if smoking cessation without NRT fails. If they

express a clear wish to receive NRT, use professional judgement when deciding whether to offer a prescription<sup>2</sup>.

- Only prescribe NRT for use once they have stopped smoking (they may set a particular date for this)<sup>3</sup>. Only prescribe 2 weeks of NRT for use from the day they agreed to stop. Only give subsequent prescriptions to women who have demonstrated, on re-assessment, that they are still not smoking<sup>4</sup>.
- Advise pregnant women who are using nicotine patches to remove them before going to bed<sup>4</sup>.
- Neither varenicline or bupropion should be offered to pregnant or breastfeeding women<sup>5</sup>.

### Recommendation 6: NHS Stop Smoking Services – meeting the needs of disadvantaged pregnant women who smoke

#### Who should take action?

NHS Stop Smoking Services.

#### What action should they take?

Ensure services are delivered in an impartial, client-centred manner. They
should be sensitive to the difficult circumstances many women who smoke
find themselves in. They should also take into account other
sociodemographic factors such as age and ethnicity and ensure provision

<sup>&</sup>lt;sup>2</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

<sup>&</sup>lt;sup>3</sup> The British National Formulary (2010) advises on use of NRT during pregnancy: 'Intermittent therapy is preferable but avoid liquorice-flavoured nicotine products'.

<sup>&</sup>lt;sup>4</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

<sup>&</sup>lt;sup>5</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

is culturally relevant. This includes making it clear how women who are non-English speakers can access and use interpreting services<sup>6</sup>.

- Involve these women in the planning and development of services<sup>5</sup>.
- Ensure services are flexible and coordinated. They should take place in locations – and at times – that make them easily accessible and should be tailored to meet individual needs<sup>5</sup>.
- Collaborate with the family nurse partnership pilot and other outreach schemes to identify additional opportunities for providing intensive and ongoing support. (Note: family nurses make frequent home visits.)
- Work in partnership with agencies that support women who have complex social and emotional needs. This includes substance misuse services, youth and teenage pregnancy support and mental health services.

### Recommendation 7 Partners and others in the household who smoke

#### Context

Interventions which are effective with the general population will not necessarily work with the partners of women who are pregnant. For example, simply providing booklets, self-help guidance or media education campaigns is not effective with this group around the time of pregnancy.

#### Who should take action?

NHS Stop Smoking Services.

#### What action should they take?

 Provide clear advice about the danger that other people's tobacco smoke poses to the pregnant woman and to the baby – before and after birth.

<sup>&</sup>lt;sup>6</sup> This is an edited extract from a recommendation that appears in 'Identifying and supporting people most at risk of dying prematurely' NICE public health guidance 15. It does not constitute a change to the original recommendation.

- Recommend not smoking around the pregnant woman, mother or baby.
   This includes not smoking in the house or car.
- Offer partners who smoke help to stop using a multi-component intervention that comprises three or more elements and multiple contacts.
   Discuss with them which options to use – and in which order, taking into account<sup>7</sup>:
  - their preferences
  - contra-indications and the potential for adverse effects from pharmacotherapies such as NRT
  - the likelihood that they will follow the course of treatment
  - their previous experience of smoking cessation aids.
- Do not favour one medication over another. Together, choose the one that seems most likely to succeed taking into account the above<sup>8</sup>.

#### Recommendation 8 Training to deliver interventions

#### Who should take action?

- Commissioners of NHS Stop Smoking Services.
- · Maternity services.
- Professional bodies and organisations.
- NHS Centre for Smoking Cessation and Training.
- Other providers of smoking cessation training which meets the national standard.

<sup>&</sup>lt;sup>7</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

<sup>&</sup>lt;sup>8</sup> This is an edited extract from a recommendation that appears in 'Smoking cessation services' NICE public health guidance 10. It does not constitute a change to the original recommendation.

- Ensure all midwives who deliver intensive stop-smoking interventions
   (one-to-one or group support levels 2 and 3) are trained to the same
   standard as NHS stop-smoking advisers. The minimum standard for these
   interventions is set by the NHS Centre for Smoking Cessation and
   Training<sup>9</sup>. They should also be provided with additional, specialised
   training and offered ongoing support and training updates<sup>10</sup>.
- Ensure all midwives who are not specialist stop-smoking advisers are trained to assess and record people's smoking status and their readiness to quit. They should also know about the health risks of smoking and the benefits of quitting and understand why it can be difficult to stop. In addition, they should know about the treatments that can help people to quit and how to refer them to local services for treatment. (Acquisition of this knowledge and skill set is part of level 1 training in brief stop-smoking interventions 11. Please note, midwives are not advised to carry out brief interventions with pregnant women. However, they are advised to use these skills to initiate a referral to NHS Stop Smoking Services.)
- Ensure midwives and NHS stop-smoking specialist advisers who work with pregnant women:
  - know how to ask them questions in such a way that encourages them to be open about their smoking
  - always recommend quitting rather than cutting down
  - have received accredited training in the use of CO monitors.
- Ensure brief stop-smoking interventions (level 1) and intensive one-to-one
  and group support to stop smoking (levels 2 and 3) are incorporated into
  pre- and post-registration midwifery training and midwives' continuing
  professional development, as appropriate.

<sup>9</sup> www.ncsct.co.uk/

<sup>&</sup>lt;sup>10</sup> For information about the NHS Centre for Smoking Cessation and Training's forthcoming specialist module go to <a href="https://www.ncsct.co.uk">www.ncsct.co.uk</a>

<sup>&</sup>lt;sup>11</sup> For the national standard for level 1 see 'Standard for training in smoking cessation treatments' (<a href="www.nice.org.uk/page.aspx?o=502591">www.nice.org.uk/page.aspx?o=502591</a>) or future updates from the NHS Centre for Smoking Cessation and Training.

- Ensure all healthcare and other professionals who work with the target group are trained in the same skills and to the same standard as those required of midwives who are not specialist smoking cessation advisers.
   This includes: GPs, practice nurses, health visitors, obstetricians, paediatricians, sonographers, midwives (including young people's lead midwives), family nurses and those working in fertility clinics, dental facilities and community pharmacies. It also includes those working in youth and teenage pregnancy services, children's centres, social services and voluntary and community organisations.
- Ensure all the healthcare and other professionals listed in the previous bullet:
  - know what support local NHS Stop Smoking Services offer and how to refer the women being targeted
  - understand the impact that smoking can have on a woman and her unborn child
  - understand the dangers of exposing a pregnant woman and her unborn child – and other children – to secondhand smoke.
- Ensure all training in relation to smoking and pregnancy addresses the:
  - barriers that some professionals may feel they face when trying to tackle smoking with a pregnant woman (for example, they may feel that broaching the subject might damage their relationship)
  - important role that partners and 'significant others' can play in helping a woman who smokes and is pregnant (or who has recently given birth) to quit. This includes the need to get them to consider quitting if they themselves smoke.

#### 2 Public health need and practice

According to research conducted by the British Market Research Bureau, in 2005 nearly a third (32%) of mothers in England smoked in the 12 months before or during pregnancy. Although nearly half (49%) gave up before the birth, three in ten (30%) were smoking again less than a year after giving birth.

One in six (17%) continued to smoke throughout their pregnancy – one in ten (11%) of them cut down the amount they smoked (British Market Research Bureau 2007).

However, other research (including studies which had biochemically validated smoking status) suggests that the proportion of women smoking before or during pregnancy is higher than this (French et al. 2007; Lawrence et al. 2005; Owen and McNeill 2001). In addition, studies using biochemical measures of exposure to tobacco smoke suggest that their intake of toxins is not actually reduced – even when they said they had cut down (Lawrence et al. 2003).

In 2005, almost four in ten mothers in England (38%) lived in a household where at least one person smoked during their pregnancy. In most cases the person who smoked was the mother's partner. A sizeable minority did give up after the woman gave birth: 15% were not smoking when the baby was aged 4–10 weeks and by the time the baby was aged 4–6 and 8–10 months almost a quarter (24%) had quit (British Market Research Bureau 2007).

Almost half of all children in the UK are exposed to tobacco smoke at home (Jarvis et al. 2000).

#### Health risks

Smoking during pregnancy can cause serious pregnancy-related health problems. These include: complications during labour and an increased risk of miscarriage, premature birth, still birth, low birth-weight and sudden unexpected death in infancy (Royal College of Physicians 1992). Smoking during pregnancy also increases the risk of infant mortality by an estimated 40% (Department of Health 2007).

The total annual cost to the NHS of smoking during pregnancy is estimated to range between £8.1 and £64 million for treating the resulting problems for mothers and between £12 million and £23.5 million for treating infants (aged 0–12 months) (Godfrey et al. 2010).

Children exposed to tobacco smoke in the womb are more likely to experience wheezy illnesses in childhood. In addition, infants of parents who smoke are

more likely to suffer from serious respiratory infections (such as bronchitis and pneumonia), symptoms of asthma and problems of the ear, nose and throat (including glue ear). Exposure to smoke in the womb is also associated with psychological problems in childhood such as attention and hyperactivity problems and disruptive and negative behaviour (Button et al. 2007). In addition, it has been suggested that smoking during pregnancy may have a detrimental effect on the child's educational performance (Batstra et al. 2003).

#### Key factors

Smoking during pregnancy is strongly associated with a number of factors including age and social economic position.

Mothers aged 20 or under are five times more likely than those aged 35 and over to have smoked throughout pregnancy (45% and 9% respectively) (British Market Research Bureau 2007). Mothers in routine and manual occupations are more than four times as likely to smoke throughout pregnancy – compared to those in managerial and professional occupations (29% and 7% respectively) (British Market Research Bureau 2007).

Pregnant women are also more likely to smoke if they are less educated, live in rented accommodation and are single or have a partner who smokes.

Almost nine in ten mothers (87%) who were smoking before or during their pregnancy said they received some type of advice or information about the habit (British Market Research Bureau 2007).

Mothers who had only been advised to give up were much more likely to quit – compared with those who were advised to cut down (36% and 8% respectively). Mothers who were only advised to cut down were more likely to take this option (69%) – less than 1% tried to quit. Mothers who received mixed messages (to stop completely and cut down) were much more likely to cut down rather than give up completely (58% and 14% respectively) (British Market Research Bureau 2007). In addition, women with partners who smoke find it harder to quit and are more likely to relapse if they do manage to quit (Fang et al. 2004).

#### 3 Considerations

The Public Health Interventions Advisory Committee (PHIAC) took account of a number of factors and issues when developing the recommendations.

- 3.1 PHIAC recognised that many of the women most likely to smoke during pregnancy live in circumstances which make it difficult for them to quit the habit. It believes that strategies which seek to address the wider socioeconomic factors linked to smoking would increase their chances of success.
- 3.2 The role of the family is important. The attitude of the family, including the woman's partner, towards smoking can have an effect on her smoking behaviour (and her health, if they smoke).
- 3.3 A range of effective interventions and services, such as NHS Stop Smoking Services, are available to help people quit smoking.

  Nevertheless, only a small number of women take up the offer of help during pregnancy or after childbirth. PHIAC believes a range of local approaches are needed to increase the number of these women who are referred to the services and who receive help.
- 3.4 PHIAC noted that the smoking, nicotine and pregnancy (SNAP) randomised control trial is currently testing the efficacy and safety of using nicotine patches with pregnant women. The results are due in 2011.
- 3.5 In studies, biochemical measures of carbon monoxide (CO) levels showed that women who said they had reduced the amount they smoked during pregnancy did not necessarily reduce their exposure to toxins. Additional evidence highlights the importance for a woman who is pregnant to quit smoking altogether rather than just cutting down. This includes research showing that children are more likely to take up the habit if their parents smoke and data on the damage for both mother and child associated with continued exposure to secondhand smoke.

- 3.6 Women who are pregnant may receive mixed messages from health professionals about the benefits of cutting down as opposed to quitting smoking altogether.
- 3.7 US-based trials show that financial incentives are an effective way to encourage women who are pregnant to quit smoking. However, rigorous UK-based research is needed to take account of any cultural differences. The committee acknowledge that there is a need to avoid a proliferation of local evaluations which may be insufficiently powered or inappropriately designed to determine whether or not incentives are effective
- 3.8 PHIAC was concerned to ensure health professionals in contact with pregnant women who smoke are not put off if their first offer of help to quit smoking is refused. As a result, the recommendations emphasise the importance of offering help to stop smoking throughout the pregnancy and beyond.
- 3.9 Professional barriers to tackling smoking among women who are pregnant or who have recently given birth include: lack of time, lack of resources and concern about jeopardising the professional relationship with the client. PHIAC believed that these issues can be addressed by referring the women for specialist help as part of normal practice.
- 3.10 Although many women quit smoking during their pregnancy, relapse rates are high and most start smoking again within 6 months of giving birth. PHIAC noted that the types of interventions that had been studied had not been effective in preventing relapse.
- 3.11 None of the studies of women who were pregnant included household members other than the partner (that is, the expectant father).
- 3.12 PHIAC acknowledged that encouraging practitioners to refer all pregnant women who smoke even those who are currently

unwilling to consider quitting – may create a need for additional stop-smoking resources. It also acknowledged that initially, at least, this may also lead to lower success rates. Nevertheless, the committee believed that higher referral rates are important in tackling smoking in pregnancy.

3.13 The cost-effectiveness model showed that interventions to encourage women who are pregnant to quit smoking were cost effective (in the main, they were more effective and less costly than not intervening). However, due to insufficient data, not all the effects of smoking during pregnancy were modelled. For instance, the model did not include the impact on subsequent infant morbidity and quality of life or healthcare costs for children aged over 5 years. If these factors had been included in the analysis, PHIAC believes the interventions would have probably been even more cost effective.

#### 4 Implementation

NICE guidance can help:

- NHS organisations, social care and children's services meet the requirements of the DH's 'Operating framework for 2008/09' and 'Operational plans 2008/09–2010/11'.
- NHS organisations, social care and children's services meet the
  requirements of the Department of Communities and Local Government's
  'The new performance framework for local authorities and local authority
  partnerships'.
- National and local organisations within the public sector meet government indicators and targets to improve health and reduce health inequalities.
- Local authorities fulfil their remit to promote the economic, social and environmental wellbeing of communities.

- Local NHS organisations, local authorities and other local public sector partners benefit from any identified cost savings, disinvestment opportunities or opportunities for re-directing resources.
- Provide a focus for multi-sector partnerships for health and wellbeing, such as local strategic partnerships.

NICE has developed tools to help organisations put this guidance into practice. For details see our website at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

#### 5 Recommendations for research

The Public Health Interventions Advisory Committee (PHIAC) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful/negative side effects.

- Within a UK context, are incentives an acceptable, effective and costeffective way to help women who smoke to quit the habit when they are pregnant or after they have recently given birth? Compared with current services, do they attract more women who smoke, do they lead to more of them completing the stop-smoking programme and do more of them quit for good? What level and type of incentive works best and are there any unintended consequences?
- 2. What are the most effective and cost-effective ways of preventing women who have quit smoking from relapsing, either during pregnancy or following childbirth?
- 3. What factors explain why some women who become pregnant spontaneously quit smoking? How do social factors (such as the smoking status of friends and family) affect any spontaneous or assisted attempt to quit smoking?

- 4. How can more women (including teenagers) who smoke and are pregnant or who have recently given birth be encouraged to use stopsmoking services?
- 5. Within a UK context, which types of self-help materials (including new media) help women who smoke to quit when they are pregnant or after they have recently given birth?
- 6. What are the most effective and cost-effective ways of helping particular groups of people who smoke to stop around the time of pregnancy? These groups include the partners of pregnant women, pregnant teenagers and pregnant women who live in difficult circumstances.

More detail on the gaps in the evidence identified during development of this guidance is provided in appendix D.

#### 6 Updating the recommendations

This guidance will be reviewed at 3 and 5 years after publication to determine whether all or part of it should be updated. Information on the progress of any update will be posted at <a href="www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

#### 7 Related NICE guidance

#### **Published**

School-based interventions to prevent smoking. NICE public health guidance 23 (2010). Available from www.nice.org.uk/guidance/PH23

Antenatal care: routine care for the healthy pregnant woman. NICE clinical guideline 62 (2008). Available from <a href="https://www.nice.org.uk/guidance/CG62">www.nice.org.uk/guidance/CG62</a>

Identifying and supporting people most at risk of dying prematurely. NICE public health guidance 15 (2008). Available from <a href="https://www.nice.org.uk/guidance/PH15">www.nice.org.uk/guidance/PH15</a>

Smoking cessation services. NICE public health guidance 10 (2008). Available from www.nice.org.uk/guidance/PH10

Community engagement. NICE public health guidance 9 (2008). Available from www.nice.org.uk/guidance/PH9

Behaviour change. NICE public health guidance 6 (2007). Available from www.nice.org.uk/guidance/PH6

Workplace interventions to promote smoking cessation. NICE public health guidance 5 (2007). Available from <a href="https://www.nice.org.uk/guidance/PH5">www.nice.org.uk/guidance/PH5</a>

Brief interventions and referral for smoking cessation in primary care and other settings. NICE public health guidance 1 (2006). Available from <a href="https://www.nice.org.uk/guidance/PH1">www.nice.org.uk/guidance/PH1</a>

Postnatal care: routine postnatal care of women and their babies. NICE clinical guideline 37 (2006). Available from <a href="http://www.nice.org.uk/guidance/CG37">http://www.nice.org.uk/guidance/CG37</a>

#### Under development

Weight management in pregnancy and after childbirth. NICE public health guidance (publication expected July 2010)

Pregnancy and complex social factors. NICE clinical guideline (publication expected August 2010)

#### 8 References

Batstra L, Hadders-Algra M, Neeleman J (2003) Effect of antenatal exposure to maternal smoking on behavioural problems and academic achievement in childhood. Early Human Development 75: 21–33

British Market Research Bureau (2007) Infant feeding survey 2005. A survey conducted on behalf of the Information Centre for Health and Social Care and the UK Health Departments. Southport: The Information Centre

Button TMM, Maughan B, McGuffin P (2007) The relationship of maternal smoking to psychological problems in the offspring. Early Human Development 83 (11): 727–32

Department of Health (2007) Review of the health inequalities infant mortality PSA target. London: Department of Health

Fang WL, Goldstein AO, Butzen AY et al. (2004) Smoking cessation in pregnancy: A review of postpartum relapse prevention strategies. The Journal of the American Board of Family Medicine 17: 264–75

French GM, Groner JA, Wewers ME et al. (2007) Staying smoke free: an intervention to prevent postpartum relapse. Nicotine and Tobacco Research 9 (6): 663–70

Godfrey C, Pickett KE, Parrot S et al. (2010) Estimating the costs to the NHS of smoking in pregnancy for pregnant women and infants. York: Department of Health Sciences, The University of York

Jarvis MJ, Goddard E, Higgins V et al. (2000) Children's exposure to passive smoking in England since the 1980s: cotinine evidence from population surveys. BMJ 321: 343–5

Lawrence T, Aveyard P, Croghan E (2003) What happens to women's self-reported cigarette consumption and urinary cotinine levels in pregnancy? Addiction 98: 1315–20

Lawrence T, Aveyard P, Cheng KK et al. (2005) Does stage-based smoking cessation advice in pregnancy result in long-term quitters? 18-month postpartum follow-up of a randomised controlled trial. Addiction 110: 107–16

Owen L, McNeill A (2001) Saliva cotinine as an indicator of cigarette smoking among pregnant women. Addiction 96 (7): 1001–6

Royal College of Physicians (1992) Smoking and the young. London: Royal College of Physicians

## Appendix A Membership of the Public Health Interventions Advisory Committee (PHIAC), the NICE project team and external contractors

#### Public Health Interventions Advisory Committee

NICE has set up a standing committee, the Public Health Interventions Advisory Committee (PHIAC), which reviews the evidence and develops recommendations on public health interventions. Membership of PHIAC is multidisciplinary, comprising public health practitioners, clinicians, local authority officers, teachers, social care professionals, representatives of the public, academics and technical experts as follows.

Professor Sue Atkinson CBE Independent Consultant and Visiting
Professor, Department of Epidemiology and Public Health, University College
London

**Mr John F Barker** Associate Foundation Stage Regional Adviser for the Parents as Partners in Early Learning Project, DfES National Strategies

**Professor Michael Bury** Emeritus Professor of Sociology, University of London. Honorary Professor of Sociology, University of Kent

Professor K K Cheng Professor of Epidemiology, University of Birmingham

**Ms Joanne Cooke** Programme Manager, Collaboration and Leadership in Applied Health Research and Care for South Yorkshire

**Mr Philip Cutler** Forums Support Manager, Bradford Alliance on Community Care

**Ms Lesley Michele de Meza** Personal, Social, Health and Economic (PSHE) Education Consultant, Trainer and Writer

**Professor Ruth Hall CB** Public Health Physician; Visiting Professor at the University of the West of England.

Ms Amanda Hoey Director, Consumer Health Consulting Limited

Mr Alasdair J Hogarth Head Teacher, Archbishops School, Canterbury

**Dr Ann Hoskins** Director, Children, Young People and Maternity, NHS North West

**Ms Muriel James** Secretary, Northampton Healthy Communities

Collaborative and the King Edward Road Surgery Patient Participation Group

**Dr Matt Kearney** General Practitioner, Castlefields, Runcorn. GP Public Health Practitioner, Knowsley PCT

**CHAIR Professor Catherine Law** Professor of Public Health and Epidemiology, UCL Institute of Child Health

**Mr David McDaid** Research Fellow, Department of Health and Social Care, London School of Economics and Political Science

Mr Bren McInerney Community Member

**Professor Susan Michie** Professor of Health Psychology, BPS Centre for Outcomes Research and Effectiveness, University College London

**Professor Stephen Morris** Professor of Health Economics, Department of Epidemiology and Public Health, University College London

**Dr Adam Oliver** RCUK Senior Academic Fellow, Health Economics and Policy, London School of Economics

**Dr Mike Owen** General Practitioner, William Budd Health Centre, Bristol

**Dr Toby Prevost** Reader in Medical Statistics, Department of Public Health Sciences, King's College London

Ms Jane Putsey Lay Member, Registered Tutor, Breastfeeding Network

**Dr Mike Rayner** Director, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

**Mr Dale Robinson** Chief Environmental Health Officer, South Cambridgeshire District Council

**Ms Joyce Rothschild** Children's Services Improvement Adviser, Solihull Metropolitan Borough Council

**Dr Tracey Sach** Senior Lecturer in Health Economics, University of East Anglia

Dr David Sloan Retired Director of Public Health

**Professor Stephanie Taylor** Professor of Public Health and Primary Care, Centre for Health Sciences, Barts and The London School of Medicine and Dentistry

Dr Stephen Walters Reader, Medical Statistics, University of Sheffield

**Dr Dagmar Zeuner** Joint Director of Public Health, Hammersmith and Fulham PCT

#### **Expert co-optees to PHIAC:**

**Doris Gaga** Smoking Cessation Counsellor, Southwark Stop Smoking Services for Pregnant Women/Parents

**Susie Hill** Health Campaign Manager, Tommy's (the baby charity)

**Richard Windsor** Professor of Public Health, George Washington University Medical Centre

#### NICE project team

Mike Kelly CPHE Director

**Antony Morgan** Associate Director

**Lesley Owen** Lead Analyst and Technical Adviser (Health Economics)

**Dylan Jones** Analyst

Karen Peploe Analyst

Emma Doohan Project manager

Palida Teelucknavan Coordinator

Sue Jelley Senior Editor

Alison Lake Editor

#### External contractors

#### **Evidence reviews**

Review 1: 'Which interventions are effective and cost effective in encouraging the establishment of smokefree homes?' was carried out by the School of Health and Related Research (ScHARR), University of Sheffield. The principal authors were: Susan Baxter, Lindsay Blank, Louise Guillaume, Josie Messina, Emma Everson-Hock and Julia Burrows.

Review 2: 'Factors aiding delivery of effective interventions' was carried out by ScHARR, University of Sheffield. The principal authors were: Susan Baxter, Lindsay Blank, Louise Guillaume, Josie Messina, Emma Everson-Hock and Julia Burrows.

Review 3: 'The health consequences of pregnant women cutting down as opposed to quitting' was carried out by ScHARR, University of Sheffield. The principal authors were: Susan Baxter, Lindsay Blank, Louise Guillaume, Josie Messina, Emma Everson-Hock and Julia Burrows.

#### Cost effectiveness

'The economic analysis of interventions for smoking cessation aimed at pregnant women' was carried out by the York Health Economics Consortium, University of York. The principal author was Matthew Taylor.

#### **Fieldwork**

The fieldwork 'Consultation on NICE draft recommendations on quitting smoking in pregnancy and after childbirth: Report to the National Institute for Health and Clinical Excellence' was carried out by Greenstreet Berman Ltd.

#### **Expert reports**

Expert report 1: 'The effectiveness of smoking cessation interventions during pregnancy: a briefing paper' was carried out by the UK Centre for Tobacco Control Studies. The principal authors were: Linda Bauld and Tim Coleman.

Expert report 2: 'Interventions to improve partner support and partner cessation during pregnancy' was carried out by the Centre of Excellence for Women's Health, British Columbia. The principal authors were: Natalie Hemsing, Renee O'Leary, Katharine Chan, Chizimuzo Okoli and Lorraine Greaves.

Expert report 3: 'Rapid review of interventions to prevent relapse in pregnant ex-smokers' was carried out by Barts and The London School of Medicine and Dentistry, London. The principal authors were: Katie Myers, Oliver West and Peter Hajek.

### Appendix B Summary of the methods used to develop this guidance

#### Introduction

The reviews, commissioned reports and economic modelling include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Public Health Interventions Advisory Committee (PHIAC) meetings provide further detail about the Committee's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in appendix E and are available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

# Guidance development

The stages involved in developing public health intervention guidance are outlined in the box below.

- 1. Draft scope released for consultation
- 2. Stakeholder meeting about the draft scope
- 3. Stakeholder comments used to revise the scope
- 4. Final scope and responses to comments published on website
- 5. Evidence reviews and economic modelling undertaken and submitted to PHIAC
- 6. PHIAC produces draft recommendations
- 7. Draft guidance (and evidence) released for consultation and field testing
- 8. PHIAC amends recommendations
- 9. Final guidance published on website
- 10. Responses to comments published on website

# Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by PHIAC to help develop the recommendations. The overarching questions were:

- 1. Which interventions are effective and cost effective in helping women to quit smoking immediately before or during pregnancy and following childbirth?
- Which interventions are effective and cost effective in encouraging partners (and 'significant others') help a woman quit smoking during her pregnancy and following childbirth?

- 3. Which interventions are effective and cost effective in preventing women who have quit smoking to take up the habit again during pregnancy and following childbirth?
- 4. Which interventions are effective and cost-effective in encouraging partners (and 'significant others') who smoke to stop smoking themselves?
- 5. Which interventions are effective and cost effective in encouraging the establishment of smokefree homes?
- 6. What factors aid delivery of effective interventions? What are the barriers to successful delivery?
- 7. What are the health consequences of pregnant women cutting down on their cigarette consumption as opposed to quitting?

These questions were made more specific for each review (see reviews for further details).

# Reviewing the evidence

## Effectiveness reviews

Three reviews of effectiveness were conducted.

# Identifying the evidence

The following databases were searched from 1990 to 2009 for: interventions that encourage smokefree homes; factors which help or discourage pregnant women who smoke to use smoking cessation interventions; and the health consequences of pregnant women cutting down as opposed to quitting.

- Applied Social Sciences Index and Abstracts (ASSIA)
- British Nursing Index
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Embase
- Maternity and Infant Care

- MEDLINE
- PsycINFO
- Science Citation Index
- Social Science Citation Index.

Web of Science Cited Reference and Google Scholar were used to search for citations and internal topic experts were consulted. In addition, the reference lists of papers and reviews that were retrieved in the search process (but not included in the review, due to study type) were sifted.

## Selection criteria

Studies were included in the effectiveness reviews if they:

- included women who smoked who were planning a pregnancy, were pregnant or had an infant aged less than 12 months
- included anyone who smoked and lived in the same dwelling as a pregnant woman or one who was planning a pregnancy, or where an infant aged less than 12 months lived
- covered interventions aimed at making homes smokefree
- addressed factors that aided the delivery of effective interventions
- looked at the health consequences of pregnant women cutting down, as opposed to quitting smoking.

Studies were excluded if they:

- focused on women who did not smoke or who lived in a smokefree household
- focused on women who smoked but were not planning a pregnancy, were not pregnant, or did not have a child aged under 12 months.

# **Quality appraisal**

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Methods for the development of NICE public health guidance' (see appendix

E). Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

# Study quality

- ++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

## **Summarising the evidence and making evidence statements**

The review data were summarised in evidence tables (see full reviews and expert reports).

The findings from the reviews and expert reports were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractors and the public health collaborating centre (see appendix A). The statements reflect their judgement of the strength (quantity, type and quality) of evidence and its applicability to the populations and settings in the scope.

## **Expert reports**

Three expert reports were conducted as follows:

Expert report 1 reviewed effective interventions for pregnant women who smoke before or during pregnancy. It identified 12 papers published between 2006 and 2009. It also included findings from the latest Cochrane review on a wider range of smoking cessation interventions for pregnant women who smoke.

Expert report 2 reviewed interventions to improve partner support and partner cessation during pregnancy. It identified 18 papers published between 1990 and 2009.

Expert report 3 reviewed interventions to prevent women who have quit smoking during pregnancy and after childbirth from taking up the habit again. It identified 35 papers published between 1990 and 2009. It also included findings from the latest Cochrane review on relapse prevention.

Further details of the databases, search terms and strategies are included in each expert report.

# Cost effectiveness

The economic analysis was based on a previous model developed for NICE's guidance on smoking cessation services. This included a sub-analysis of pregnant women (<a href="https://www.nice.org.uk/guidance/PH10">www.nice.org.uk/guidance/PH10</a>).

# **Cost-effectiveness analysis**

The model included additional data from the most recent updated Cochrane review of smoking cessation interventions for pregnant women (2009).

A number of assumptions were made which could underestimate or overestimate the cost effectiveness of the interventions (see review modelling report for further details). The results are reported in: 'The economic analysis of interventions for smoking cessation aimed at pregnant women'. They are available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

# **Fieldwork**

Fieldwork was carried out to evaluate how relevant and useful NICE's recommendations were for practitioners and how feasible it would be to put them into practice. It was conducted with a wide range of practitioners who are involved in smoking cessation work with women during pregnancy and following childbirth. This included those working in maternity services, NHS stop-smoking services, smoking cessation helpline services primary care, schools and children's centres.

The fieldwork was carried out by Greenstreet Berman Ltd and comprised:

- Eight workshops in Birmingham, London, and Manchester and involving a range of health professionals from around the country.
- Six focus groups carried out in primary care trusts in Bristol, Dudley,
   Leicester, Liverpool, Manchester and Slough.

The fieldwork was commissioned to ensure there was ample geographical coverage. The main issues arising are set out in appendix C under 'fieldwork findings'. The full fieldwork report, 'Consultation on NICE draft recommendations on quitting smoking in pregnancy and after childbirth: Report to the National Institute for Health and Clinical Excellence', is available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>

## How PHIAC formulated the recommendations

At its meeting in October 2009, PHIAC considered the evidence of effectiveness, expert reports and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- whether, on balance, the evidence demonstrates that the intervention can be effective or is inconclusive
- where there is an effect, the typical size of effect
- whether the evidence is applicable to the target group and context covered by this guidance.

PHIAC developed draft recommendations through informal consensus, based on the following criteria.

- Strength (type, quality, quantity and consistency) of the evidence
- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.

- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- · Balance of harms and benefits.
- Ease of implementation and any anticipated changes in practice.

Where possible, recommendations were linked to an evidence statement(s) (see appendix C for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

The draft guidance, including the recommendations, was released for consultation in December 2009. At its meeting in March 2010, PHIAC amended the guidance in light of comments from stakeholders, experts and the fieldwork. The guidance was signed off by the NICE Guidance Executive in June 2010.

# Appendix C The evidence

This appendix lists evidence statements from three reviews produced by a public health collaborating centre and three expert reports provided by external contractors (see appendix A) and links them to the relevant recommendations. (See appendix B for the key to quality assessments.) The evidence statements are presented here without references – these can be found in the full reviews and the expert reports (see appendix E for details). It also sets out a brief summary of findings from the economic analysis.

The three reviews of effectiveness are:

- Review 1: 'Which interventions are effective and cost effective in encouraging the establishment of smokefree homes?'
- Review 2: 'Factors aiding delivery of effective interventions'
- Review 3: 'The health consequences of pregnant women cutting down as opposed to quitting'.

The three expert reports are:

- Expert report 1: 'The effectiveness of smoking cessation interventions during pregnancy: a briefing paper'
- Expert report 2: 'Interventions to improve partner support and partner cessation during pregnancy'
- Expert report 3: 'Rapid review of interventions to prevent relapse in pregnant ex-smokers'.

**Evidence statement number R2.1** indicates that the linked statement is numbered 1 in review 2. **Evidence statement ER1.1** indicates that the linked statement is numbered 1 in expert report 1.

The reviews, expert reports and economic analysis are available at www.nice.org.uk/guidance/PH26

Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by **IDE** (inference derived from the evidence) below.

Where PHIAC has considered other evidence, it is linked to the appropriate recommendation below. It is also listed in the additional evidence section of this appendix. This includes evidence used to develop other NICE guidelines and guidance.

**Recommendation 1**: evidence statements R2.1, R2.2, R2.3, R2.4, R2.5, R2.6, R2.7, R2.8, R2.9, R2.10, R2.11, ER1.6, ER1.10, ER1.11; IDE

**Recommendation 2**: evidence statements R2.1, R2.2, R2.3, R2.4, R2.5, R2.6, R2.7, R2.8, R2.9, R2.11, ER1.6, ER1.10; IDE

**Recommendation 3**: evidence statements R2.2, R2.3, R2.4, R2.5, R2.9, R2.11, R2.12, ER 1.5, ER1.8, ER1.9, ER1.10, ER1.12; IDE; additional evidence PH10

**Recommendation 4**: evidence statements R2.1, R2.2, R2.3, R2.4, R2.5, R2.6, R2.7, R2.8, R2.9, R2.10, R2.11, R2.12, ER1.1, ER1.2, ER1.5, ER1.6, ER1.8, ER1.12; IDE

Recommendation 5: evidence statements ER1.3, ER1.4; IDE

**Recommendation 6**: evidence statements R2.3, R2.12, ER1.6, ER1.8, ER1.9, ER1.12; IDE; additional evidence PH15

Recommendation 7: evidence statements ER2.2; IDE

**Recommendation 8**: evidence statements R2.1, R2.2, R2.3, R2.4, R2.6, R2.7, R2.10, R2.11, R2.12, ER1.10, ER1.11, ER1.12; IDE

## Evidence statements

Please note that the wording of some evidence statements has been altered slightly from those in the evidence reviews to make them more consistent with each other and NICE's standard house style.

## **Evidence statement R2.1**

Two qualitative studies (one [+] Northern Ireland and one [-] USA) and five survey studies (France, UK, Australia, New Zealand and South Africa) provide evidence that not all staff ask all pregnant women about their smoking status during consultations. One (-) study reports data from a lower income/educated population. Three studies (one [++], one [+], one [-] and one narrative provide evidence that staff may not ask about smoking status because of concerns regarding damaging the relationship between themselves and a pregnant woman.

## **Evidence statement R2.2**

Five qualitative studies (one [-] USA and four [+] from South Africa, Sweden, Northern Ireland and USA) and three surveys (France, Australia and GB) provide evidence that the information and advice currently provided by health professionals is perceived as insufficient or inadequate by some women and by professionals themselves. There is the suggestion that advice could be more detailed and explicit, and that professionals find discussion of individual smoking behaviours challenging. Three of the studies (one [-] and two [+]) report data from a lower income/lower educated/deprived area.

## **Evidence statement R2.3**

Five qualitative papers (three [+] from Sweden, South Africa and GB and two [-] from GB and USA) describe how the style or way that information/advice is communicated to pregnant women smokers can impact on how the advice or information is received. Concerns regarding advice being construed as nagging or preaching are reported, together with the recommendation that a more caring, empathetic approach may be helpful.

## **Evidence statement R2.4**

One qualitative study ([+] Northern Ireland) and four surveys (Australia, France, New Zealand and USA) provide evidence that there is variance in practice among staff in regard to the type of intervention offered during and following a consultation, such as whether a leaflet is offered, whether there is

referral on to a specialist programme, or whether ongoing personal support is offered.

## **Evidence statement R2.5**

There is evidence from one qualitative study ([+] South Africa) and two surveys (GB and USA) that there is limited knowledge/availability/use of guidelines or protocols in practice. There is evidence from one survey (Australia) that having guidelines/protocols in place may be associated with an increase in the number of smoking interventions offered.

## **Evidence statement R2.6**

Evidence from four qualitative studies (one [++] New Zealand and three [+] from Sweden, South Africa and USA) three surveys (GB, France and New Zealand) and a narrative report (USA) suggests that record-keeping practices and follow-up enquiries may be inconsistent among practitioners. Pregnant women smokers and recent mothers differed in their views regarding the frequency with which they should be asked about their smoking.

## **Evidence statement R2.7**

Three qualitative studies (one [++] New Zealand and two [+] from South Africa and Sweden), seven surveys (four from Australia, two from USA and one GB) and one narrative report (USA) suggest that staff perceive that they have limited skills and knowledge to implement successful smoking cessation interventions.

## **Evidence statement R2.8**

Two qualitative studies (one [+] South Africa and one [-] Australia), seven surveys (three from Australia, two from USA, one New Zealand and one GB) and one narrative report (USA) provide evidence that staff perceive that lack of time is a significant barrier to the implementation of smoking cessation interventions.

## **Evidence statement R2.9**

One qualitative study ([+] South Africa), six surveys (four from Australia and two from USA) and narrative from one study (USA) suggest that staff perceive

that limited resources, in the form of either staff or patient education materials, impact on the delivery of interventions. These papers report findings from Australia and the USA – their applicability to the UK may need to be considered.

#### **Evidence statement R2.10**

Two qualitative studies (one [+] Sweden and one [+] South Africa) and seven surveys (three from Australia, two from USA, one New Zealand and one GB) suggest that staff perceptions regarding the limited effectiveness of interventions may impact on their delivery of services. One paper (USA) describes a lack of firm reasons for non-attendance given by women who did not attend a smoking intervention programme.

## **Evidence statement R2.11**

Four surveys (two from Australia, one New Zealand and one GB) provide evidence that typical practice in regard to smoking cessation advice and management of care can vary between doctors and midwives. It is reported that GPs are more likely to advise women to quit smoking completely, whereas midwives are more likely to advise gradual reduction. Also, the evidence suggests that midwives are more likely to refer on to other agencies and record smoking status. GPs may be more likely than midwives to raise the subject of smoking at subsequent consultations.

## **Evidence statement R2.12**

One qualitative study ([+] GB) and two narrative reports (both USA) describe obstacles to pregnant women smokers accessing services as including: the length of sessions; difficulty making telephone contact; and a lack of transport or child care. It is suggested that domiciliary or very local services, the provision of crèche facilities, appointment systems or telephone counselling could be suitable service delivery options. One study (USA) suggests, however, that telephone support services may have poor success in terms of contact rates.

## **Evidence statement ER1.1**

There is good evidence from one recently updated systematic review (++) on the effectiveness of interventions for promoting smoking cessation in pregnancy.

The review included 72 trials. Pooled results show that cessation interventions reduce smoking in late pregnancy (risk ratio [RR] 0.94, 95% confidence interval [CI] 0.93 to 0.96) and reduce incidences of low birth weight (RR 0.83, 95% CI 0.73 to 0.95) and pre-term births (RR 0.86, 95% CI 0.74 to 0.98) while increasing birth weight by a mean of 53.91 g (95% CI 10.44 g to 95.38 g).

The overall finding of the updated review is that smoking cessation interventions used in early pregnancy can reduce smoking in later pregnancy by around 6% (or 3% using studies least prone to bias).

## **Evidence statement ER1.2**

There is good evidence from one recently updated systematic review (++) on the effectiveness of financial incentives for promoting smoking cessation in pregnancy. Four trials in the review examined financial incentives. A meta-analysis found that financial incentives paid to pregnant women to promote smoking cessation were found to be significantly more effective than other intervention strategies (RR 0.76, 95% CI 0.71 to 0.81).

## **Evidence statement ER1.3**

There is mixed evidence from one recently updated systematic review (++) and one recent trial ([++] USA) (not included in the review) on the effectiveness of nicotine replacement therapy (NRT) for promoting smoking cessation in pregnancy.

In the review, meta-analysis of data from five trials found NRT to be effective (RR 0.95 Cl 0.92 to 0.98). However, a large, double-blind, placebo-controlled trial, published after the review searches were completed, found no evidence that NRT was effective for smoking cessation in pregnancy (RR 0.96, 95% Cl 0.85-1.09).

## **Evidence statement ER1.4**

There is no evidence that NRT either increases or decreases low birthweight. There are insufficient data to form judgements about any impact of NRT on stillbirth or special care admissions (two [++]).

## **Evidence statement ER1.5**

There is good evidence from one recent systematic review (++) on the effectiveness of self-help interventions for smoking cessation in pregnancy, although the extent of UK evidence is limited.

Fifteen trials were included in the review and 12 in the primary meta-analysis which found that self-help interventions were effective (Odds ratio [OR] 1.83, 95% CI 1.23-2.73). A further meta-analysis failed to find evidence that more intensive self-help interventions had greater impact than less intensive ones.

## **Evidence statement ER1.6**

There is evidence from four UK studies (all [+]) that NHS Stop Smoking Services are effective in supporting pregnant women to stop smoking.

The NHS Stop Smoking Service interventions for pregnant women described in these articles consist of a combination of behavioural support (delivered in a range of settings and formats) and NRT (for most but not all women). They report varied outcomes but those that included 4-week post-quit date outcomes reported quit rates of between 32% and 48%. However, evidence from a national study of smoking cessation services for pregnant women in Scotland found that the reach and effectiveness of services varied significantly between health boards. Some areas offered no tailored (specialist) smoking cessation interventions for pregnant women.

#### **Evidence statement ER1.8**

There is limited evidence about whether the form of delivery can affect the effectiveness of smoking cessation interventions for pregnant women.

One trial ([++] UK) found some evidence that stage-matched interventions for smoking cessation in pregnancy were more effective, particularly in improving

women's readiness to quit, but concluded that it was difficult to interpret this finding as the stage-based interventions were also more intensive. Another qualitative study ([+] UK) summarised the delivery characteristics of stop smoking services for pregnant women that were perceived to be successful by key stakeholders. These characteristics included: training of midwives in how to refer pregnant smokers to specialist services, offering NRT to almost all clients, having an efficient system of providing prescriptions, offering home visits, and providing intensive multi-session behavioural support delivered by specialist staff.

#### **Evidence statement ER1.9**

There is limited evidence that the site or setting of the intervention influences the effectiveness of smoking cessation interventions for pregnant women in the UK. One study ([+] UK) found that most stop smoking services in Scotland offered home visits by trained advisers to pregnant women. An analysis of routine service data suggested that, for those home-based services for which data on engagement (whether a woman attended the first appointment with a specialist adviser) were available, about 50% of those referred engaged compared with 20% for clinic-based services.

## **Evidence statement ER1.10**

There is good evidence that women in the UK under-report smoking during pregnancy and that CO monitoring can aid in the identification of pregnant smokers. Two studies (one [++] and one [+]) found that around one in four pregnant women in the west of Scotland do not accurately disclose their smoking status when asked during the booking visit with a midwife. One of these studies described how routine CO monitoring in antenatal clinics, if implemented consistently, can improve the accurate identification of pregnant smokers and facilitate referral to smoking cessation services.

# **Evidence statement ER1.11**

There is very preliminary evidence from two observational studies that opt-out referral pathways can increase the number of women who engage with NHS

stop smoking services and result in larger numbers of women quitting smoking, when compared with opt-in referral pathways.

## **Evidence statement ER1.12**

Two studies (one [+] UK and one [-] UK) explored pregnant women's views about smoking cessation services. Barriers to accessing services included, among others, feeling unable to quit, lack of knowledge about services, difficulty of accessing services, fear of failing and concerns about being stigmatised.

## **Evidence statement ER2.2**

There is moderate evidence that multi-component interventions that include free nicotine replacement therapies are effective in encouraging partners who smoke to stop smoking. Nine studies (five [+] from USA, the Netherlands, Australia and two from the UK, one [++] Australia, three [-] from Sweden, China and Norway) examined whether specific interventions were effective in encouraging partners and 'significant others' who smoke to stop smoking. Interventions that had non-significant outcomes include: a media education campaign, partner-delivered booklet, counselling, biofeedback-based interventions, and self-help guidance.

Two randomised control trials from the US and Australia had significant outcomes. These interventions offered free NRT patches to partners, in conjunction with smoking cessation resources and multiple telephone counselling sessions which encouraged partner support, or along with a minimal intervention which included video and print materials on smoking cessation and multiple contacts to address the male partner's smoking. However, the effect of treatment on overall quit rates was not sustained at follow-up periods.

Applicability: both studies with significant findings took place outside of the UK. Therefore, findings may not be directly relevant to the UK.

## Additional evidence

'Smoking cessation services' NICE public health guidance 10 (2008).

• 'Identifying and supporting people most at risk of dying prematurely' NICE public health guidance 15 (2008).

## Cost-effectiveness evidence

The economic analysis was based on a previous model developed for NICE's guidance on smoking cessation services. This model included a sub-analysis of pregnant women (public health guidance 10 available at <a href="https://www.nice.org.uk/guidance/PH10">www.nice.org.uk/guidance/PH10</a>). For the purposes of this guidance, it used data from the most recently updated Cochrane review of smoking cessation interventions for pregnant women (2009).

The cost-effectiveness model showed that interventions to encourage women who are pregnant to quit smoking were cost effective (in the main, they were more effective and less costly than no intervention).

However, due to insufficient data, not all the effects of smoking during pregnancy were modelled. For instance, the model did not include the impact on infant morbidity and quality of life, or on healthcare costs for children aged over 5 years. PHIAC took the view that, had these factors been included in the analysis, the interventions would have probably been shown to be more cost effective.

# Fieldwork findings

Fieldwork aimed to test the relevance, usefulness and feasibility of putting the recommendations into practice. PHIAC considered the findings when developing the final recommendations. For details, go to the fieldwork section in appendix B and see the full report: 'Consultation on NICE draft recommendations on quitting smoking in pregnancy and after childbirth: Report to the National Institute for Health and Clinical Excellence'.

Fieldwork participants who work with women who smoke during pregnancy and following childbirth were generally positive about the recommendations and their potential to help women quit smoking during pregnancy or following childbirth.

Participants pointed out that many areas use a referrals system and that this tends to operate on an 'opt-in' basis. The draft recommendations suggested an opt-out approach which would increase referrals and may lead to the need for more resources.

Participants felt that it was unlikely referrals would come through pharmacists and GPs. However, other professionals had been found to be an invaluable source of support for helping pregnant women to quit smoking, particularly children's centre staff.

Most participants believed the recommendations were useful in that they pulled together a range of information in one place. They were also seen as practicable and relevant. However, clarity was needed in some specific areas.

# Appendix D Gaps in the evidence

The Public Health Interventions Advisory Committee (PHIAC) identified a number of gaps in the evidence relating to the interventions under examination, based on an assessment of the evidence. These gaps are set out below.

- 1. There is a lack of evidence on how to prevent pregnant women who have given up smoking from taking up the habit again after giving birth.
- 2. There is limited evidence on the effectiveness and cost effectiveness of interventions aimed at:
  - encouraging partners and 'significant others' to help pregnant women to stop smoking
  - b. helping partners and 'significant others' who smoke to quit
  - c. establishing smokefree homes
  - d. helping women from certain demographic groups (for example, teenage girls and people from some minority ethnic groups) who smoke to quit.
- 3. There is limited, UK-specific evidence on:
  - a. how to increase the contact smoking cessation services have with pregnant women who smoke
  - b. the effectiveness and cost effectiveness of incentives to encourage women who are pregnant or postpartum to stop smoking
  - c. which elements of self-help materials are effective
  - d. the effectiveness of new media in encouraging pregnant women to give up smoking.
- 4. There is limited evidence on how and why some women spontaneously quit smoking when they become pregnant.

The Committee made 6 recommendations for research. These are listed in section 5.

# **Appendix E Supporting documents**

Supporting documents are available at <a href="https://www.nice.org.uk/guidance/PH26">www.nice.org.uk/guidance/PH26</a>
These include the following.

## • Evidence reviews:

- Review 1: 'Which interventions are effective and cost effective in encouraging the establishment of smokefree homes?'
- Review 2: 'Factors aiding delivery of effective interventions'
- Review 3: 'The health consequences of pregnant women cutting down as opposed to quitting'.

# • Expert reports:

- Expert report 1: 'The effectiveness of smoking cessation interventions during pregnancy: a briefing paper'
- Expert report 2: 'Interventions to improve partner support and partner cessation during pregnancy'
- Expert report 3: 'Rapid review of interventions to prevent relapse in pregnant ex-smokers'.
- Economic modelling: 'The economic analysis of interventions for smoking cessation aimed at pregnant women'.
- Fieldwork report: Consultation on NICE draft recommendations on quitting smoking in pregnancy and after childbirth: Report to the National institute for Health and Clinical Excellence'.
- A quick reference guide for professionals whose remit includes public health and for interested members of the public. This is also available from NICE publications (0845 003 7783 or email publications@nice.org.uk – quote reference number N2198).

For information on how NICE public health guidance is developed, see:

 'Methods for development of NICE public health guidance (second edition, 2009)' available from <a href="https://www.nice.org.uk/phmethods">www.nice.org.uk/phmethods</a>

 'The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)' available from <a href="https://www.nice.org.uk/phprocess">www.nice.org.uk/phprocess</a>